SLOVENSKI STANDARD

SIST EN 45502-2-2:2008

01-junij-2008

Nadomeġļ a:

SIST EN 50061:1995

SIST EN 50061:1995/A1:1998

Aktivni vsadljivi medicinski elementi - 2-2. del: Posebne zahteve za aktivne vsadljive medicinske elemente, namenjene za zdravljenje tahiaritmije (vkljuļ uje vsadljive defribilatorje)

Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)

Aktive implantierbare Medizingeräte - Teil 2-2: Besondere Festlegungen für aktive implantierbare medizinische Produkte zur Behandlung von Tachyarrhythmie (einschließlich implantierbaren Defibrillatoren)

Dispositifs médicaux implantables actifs - Partie 2-2: Exigences particulières pour les dispositifs médicaux implantables actifs destinés au traitement des tachyarythmies (y compris les défibrillateurs implantables)

Ta slovenski standard je istoveten z: **EN 45502-2-2:2008**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN 45502-2-2:2008 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-2-2

March 2008

ICS 11.040.40

Partially supersedes EN 50061:1988 + A1:1995

English version

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This European Standard was approved by CENELEC on 2007-05-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 45502-2-2:2008 E

Foreword

This European Standard was prepared by the CEN/CENELEC Joint Working Group on ACTIVE IMPLANTABLE MEDICAL DEVICES (CEN/CLC JWG AIMD).

The text of the draft was submitted to the formal vote and was approved by CENELEC as EN 45502-2-2 on 2007-05-01.

This European Standard, together with EN 45502-2-1:2003, supersedes EN 50061:1988 + A1:1995 (+ corrigendum October 1995).

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2008-10-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-05-01

The requirements of this Particular Standard supplement or modify those of EN 45502-1:1997, active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer.

This European Standard has been prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC JWG AIMD). Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC.

This European Standard has been prepared under mandates given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports the essential requirements of Directive 90/385/EEC Council Directive of June 1990 on the approximation of the laws of the Member states relating to active implantable medical devices.

Although both this Particular Standard and the Directive deal with the same products, the structure and purpose of the two documents are different. Annex AA of this Particular Standard correlates the requirements of the Directive with the subclauses of EN 45502-1:1997 and of this Particular Standard. Annex BB provides references in the other direction, from this European Standard to the Directive. Annex CC is a rationale providing some further explanation of the subclauses of this Particular Standard.

Contents

Introduction

This Particular Standard specifies particular requirements for IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia, to provide basic assurance of safety for both patients and users.

An external defibrillator is a MEDICAL DEVICE used, in the emergency setting, to deliver a high-energy shock to the heart, by means of ELECTRODES applied to the external chest wall, in patients suffering ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to restore normal heart action. External defibrillators may also be used, in emergency or elective settings, to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock, synchronised to the intrinsic cardiac rhythm, a procedure known as CARDIOVERSION. In patients known to be at risk of such arrhythmias, due to the occurrence of previous episodes or the presence of specific pre-disposing cardiac conditions, an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may be implanted to perform similar functions. The implantable device, which is much smaller than an external defibrillator, is contained within a sealed, encapsulating enclosure. It generates high voltage PULSES from an enclosed, miniature, electrical battery. The PULSES are transmitted to the heart by means of implanted, insulated conductors with ELECTRODES (LEADS) The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may also incorporate other sensing and pacing functions, such as rate support for bradycardia and ANTITACHYCARDIA PACING (ATP) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator may be adjusted non-invasively by means of an electronic device, known as a programmer.

This Particular Standard is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES, programmers and the related software. (Bradyarrhythmia pacing functions are dealt with in EN 45502-2-1).

The requirements of this Particular Standard supplement or modify those of EN 45502-1:1997, *Active Implantable Medical Devices – Part 1: General requirements for safety, marking and for the information to be provided by the manufacturer*, hereinafter referred to as the General Standard. The requirements of this particular standard take priority over those of the General Standard.

Figures or tables that are additional to those of the General Standard are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Annex DD describes a coding system that may be used to designate tachyarrhythmia therapy modes. Annex EE defines the tissue equivalent interface circuits and low pass filter required for some compliance tests. Annex FF describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex EE. Annex GG defines the method of calibrating the injection network defined by Annex EE. All annexes except Annex EE and Annex GG are informative.

1 Scope

This Part 2-2 of EN 45502 specifies requirements that are applicable to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance.

This part of EN 45502 is also applicable to some non-implantable parts and accessories of the devices (see Note 1).

The characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD shall be determined by either the appropriate method detailed in this particular standard or by any other method demonstrated to have accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this Particular Standard shall apply.

Any aspect of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias is covered by EN 45502–2-1 *Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (Pacemakers).*

NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE may in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this European Standard, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of devices are not covered by this standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

This clause of the General Standard aplies except as follows:

Additional references:

Publication	Year	Title
EN 980		Graphical symbols for use in the labelling of medical devices
EN 28601		Data elements and interchange formats – Information interchange – Representation of dates and times (ISO 8601 + technical corrigendum 1)
EN 45502-1		Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 45502-2-1		Active implantable medical devices – Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)

EN 60068-2-27	Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock (IEC 60068–2–27)
EN 60068-2-47	Environmental testing – Part 2-47: Tests – Mounting of specimens for vibration, impact and similar dynamic tests (IEC 60068-2-47)
EN 60068-2-64	Environmental testing – Part 2: Test methods – Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64)
IEC 60878	Graphical symbols for electrical equipment in medical practice
ISO 5841-3 + corr. 1	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers
ISO 11318	Cardiac defibrillators – Connector assembly DF-1 for implantable defibrillators – Dimensions and test requirements
ANSI/AAMI PC69	Active implantable medical devices – Electromagnetic compatibility – EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

3 Definitions

This clause of the General Standard applies except as follows:

Additional definitions:

3.3.1
adaptor
special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

3.3.2
implantable cardioverter defibrillator (ICD)
ACTIVE IMPLANTABLE MEDICAL DEVICE comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S) that is intended to detect and correct tachycardias and fibrillation by application of CARDIOVERSION/-DEFIBRILLATION PULSE(S) to the heart

3.3.3
implantable pulse generator (IPG)
part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, including the power supply and electronic circuit that produces an electrical output

NOTE For purposes of this Particular Standard, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

3.3.4
sensitivity (sensing threshold)
minimum signal required to control consistently the function of the IMPLANTABLE PULSE GENERATOR [see 6.1.5]

3.3.5
sensor
special part of an IMPLANTABLE PULSE GENERATOR that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

3.5.1
electrode
electrically conducting part (usually the termination of a LEAD), which is designed to form an interface with body tissue or body fluid

3.5.2
endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart

3.5.3
epicardial lead
LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart

3.5.4
transvenous
approach to the heart through the venous system

3.5.5
insertion diameter (of a lead)
minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) may be inserted

3.5.6
lead conductor resistance
R_c ohmic resistance between the ELECTRODE and the corresponding LEAD connector TERMINAL [see 6.2.1 of EN 45502-2-1]

3.5.7
lead pacing impedance
Z_p impedance that is formed by the ratio of a voltage PULSE to the resulting current [see 6.2.2 of EN 45502-2-1]. The impedance is composed of the ELECTRODE/tissue interface and the LEAD CONDUCTOR RESISTANCE

3.5.8
lead sensing impedance
Z_s source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR [see 6.2.3 of EN 45502-2-1]

3.9.1
model designation
name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

3.9.2
serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same MODEL DESIGNATION

3.20.1
beat
ordered spontaneous activity of the heart

3.20.2
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR other than CD PULSE [see 3.3.5] intended to stimulate the myocardium

3.20.3
pulse amplitude
amplitude of the PULSE measured according to the procedure in 6.1.1 of EN 45502-2-1

3.20.4
pulse duration
duration of the PULSE, measured between two reference points specified in this Particular Standard [see 6.1.1 of EN 45502-2-1]

3.20.5
pulse interval
interval between equivalent points of two consecutive PULSES
[see 6.1.1 of EN 45502-2-1]

3.20.6
basic pulse interval
PULSE INTERVAL in absence of sensed cardiac or other electrical influence

3.20.7
automatic sensitivity control
automatic adjustment of the SENSITIVITY in response to available physiological signals

3.21.1
beginning of service; BOS
when an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for being placed on the market

3.21.2
end of service; EOS
when the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

3.21.3
prolonged service period; PSP
period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR continues to function as specified by the manufacturer
[EN 45502-2-1, 3.20.4, modified]

3.21.4
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR'S service life

3.21.5
recommended replacement time; RRT
when the POWER SOURCE INDICATOR reaches the value set by the manufacturer of the IMPLANTABLE PULSE GENERATOR for its recommended replacement. This indicates entry into the PROLONGED SERVICE PERIOD

3.21.6
use-before-date
date after which the manufacturer recommends that the ACTIVE IMPLANTABLE MEDICAL DEVICE should not be implanted

3.22.1
antitachycardia pacing; ATP
cardiac pacing sequences intended to terminate re-entry tachycardias

3.22.2
arrhythmia detection interval
interval below which the IMPLANTABLE PULSE GENERATOR will classify a rhythm as a tachyarrhythmia

3.22.3
atp only device
IMPLANTABLE PULSE GENERATOR capable of delivering rapid sequences of pacing PULSES to terminate ventricular (VT) and atrial (AT) tachycardia and atrial fibrillation (AF)

3.22.4
cardioversion
termination of atrial tachyarrhythmia or ventricular tachycardia by PULSE(S) synchronized to cardiac events

3.22.5
cardioversion/defibrillation pulse (CD pulse)
high energy mono-phasic, biphasic, or multiphasic PULSE intended to restore normal rhythm by shocking the heart

3.22.6
capacitor formation
any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at least ten min

3.22.7
cardioversion/defibrillation lead (CD lead)
LEAD used to conduct a CD PULSE from the IMPLANTABLE PULSE GENERATOR to the heart

3.22.8
charge time
the time required to charge the high voltage capacitors to a specified CD PULSE ENERGY

3.22.9
delivered cardioversion/defibrillation pulse energy (delivered CD pulse energy)
total energy delivered to a standard load (50 Ω) by all phases of a CD PULSE, measured according to 6.1.3

3.22.10
defibrillation
termination of fibrillation

3.22.11
ICD output voltage
peak voltage of the CARDIOVERSION/DEFIBRILLATION PULSE(S), measured according to 6.1.2

3.22.12
terminal
electrically separate conductive device connection

4 Symbols and abbreviations (optional)

This clause of the General Standard applies.

5 General requirements for non-implantable parts

This clause of the General Standard applies.

6 (Vacant)

Replacement:

6 Measurement of IMPLANTABLE PULSE GENERATOR and LEAD characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8.2].

CAUTION The tests in this subclause may employ the use of high voltage. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

The measurements shall be made with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 °C ± 2 °C.

The overall measurement accuracy for each test shall be within the limits ± 5 %.

6.1.1 Measurement of the bradyarrhythmia characteristics

Measurement of the bradyarrhythmia characteristics of the IMPLANTABLE PULSE GENERATOR shall be performed using the appropriate methods specified in 6.1 of EN 45502-2-1. The bradyarrhythmia characteristics shall be measured with the tachyarrhythmia therapies inactivated.

6.1.2 Measurement of ICD OUTPUT VOLTAGE

NOTE This clause does not apply to ATP ONLY DEVICES.

Procedure: Use an oscilloscope, with input impedance of nominal 1 MΩ, ≤ 30 pF.

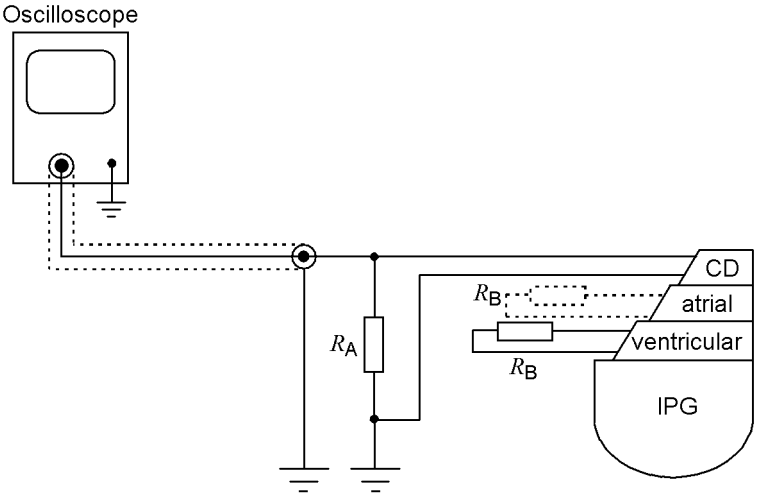

Figure 101 – Measurement of CD PULSE characteristics

The IMPLANTABLE PULSE GENERATOR shall be connected to the oscilloscope as shown in Figure 101. TERMINALS of the IMPLANTABLE PULSE GENERATOR intended to deliver a CD PULSE shall be connected to a low inductance load of 50 Ω ± 1 % (R_A). Other inputs/outputs shall be connected to loads of 500 Ω ± 5 % (R_B). The oscilloscope shall be adjusted to display one phase of the CD PULSE.

The IMPLANTABLE PULSE GENERATOR shall be programmed to the maximum CD PULSE ENERGY setting.

The ICD OUTPUT VOLTAGE (V_{max}) shall be determined by recording the peak amplitude of the voltage across the resistor R_A [see Figure 101 and Figure 102].

The procedure shall be repeated for each type of CD PULSE (i.e. monophasic, biphasic waveform).

The entire procedure shall be repeated for the other required CD PULSE ENERGY settings [see 28.8.2 d) 2)].

The results shall be expressed in volts (V) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].

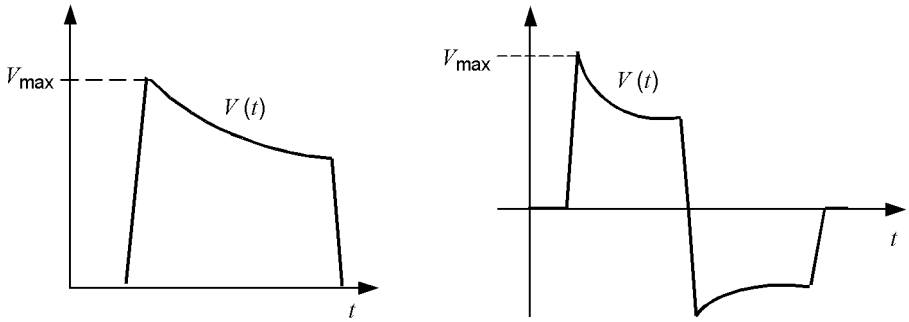

Figure 102 – Measurement of ICD OUTPUT VOLTAGE

6.1.3 Measurement of delivered CD PULSE ENERGY

NOTE This clause does not apply to ATP ONLY DEVICES.

Procedure: Use the oscilloscope and measurement set-up specified in 6.1.2.

The oscilloscope shall be adjusted to display one CD PULSE. The IMPLANTABLE PULSE GENERATOR shall be programmed to deliver the maximum CD PULSE ENERGY setting.

The CD PULSE shall be determined by recording the voltage waveform $V_{(t)}$ [see Figure 102] across the resistor R_A [see Figure 101]. The delivered CD PULSE ENERGY, W, shall be calculated by applying the equation:

$$W = \int_0^{Tp} \frac{V^2(t)}{R_A} dt$$

where:

T_p = Duration (all phases) of the CD PULSE

$V_{(t)}$ = Instantaneous voltage

R_A = 50 Ω

For devices with more than two output TERMINALS, the delivered CD PULSE ENERGY (W) shall be determined by the sum of the energies delivered from each TERMINAL, as measured by the manufacturer's disclosed method.

The entire procedure shall be repeated for the other required CD PULSE energy settings [see 28.8.2 d) 2)].

The result shall be expressed in Joules (J) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].